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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,609	09/23/2003	John D. Kantor	PA 1484 (1737.2170001/TUM)	9761
28390	7590	09/21/2004	EXAMINER	
MEDTRONIC VASCULAR, INC.				
IP LEGAL DEPARTMENT				
3576 UNOCAL PLACE				
SANTA ROSA, CA 95403				
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/667,609	Applicant(s) KANTOR, JOHN D.	
	Examiner Catherine S. Williams	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 29-33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-28 is/are allowed.
- 6) ☒ Claim(s) 1, 8, 9 and 12 is/are rejected.
- 7) ☒ Claim(s) 2-7, 10 and 11 is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date <u>2/5/04</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p> |
|---|--|

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-28, drawn to a catheter, classified in class 604, subclass 103.04.
- II. Claims 29-33, drawn to a method of making, classified in class 604, subclass 500.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be manufactured using a molding process instead of extrusion.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Rae Lynn Prengaman on 9/17/2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 10-28.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Claim Objections

Claim 2 is objected to because of the following informalities: the recitation of "said crown portions" should be --a crown portion of said node--. Appropriate correction is required.

Claims 7 and 26 are objected to because of the following informalities: the recitation of "the balloon catheter" should be --the catheter--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,8-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodden (USPN 5,411,479) in view of McDonnell et al (USPubN 2004/0059291). Bodden teaches a balloon catheter including a shaft with an interior surface having a plurality (4) of alternating arms and nodes. See figure 4. An inflation lumen (124) extends through all of the nodes. See figure 4.

Bodden meets the claim limitations as described above but fails to include a cut and a guide member. However, McDonnell discloses a balloon catheter and guidewire exchange system that includes a cut (124) and guide member (102) to facilitate easy insertion and removal of a guidewire into the lumen of the indwelling catheter.

At the time of the invention, it would have been obvious to incorporate the cut and guidewire member as taught by McDonnell into the invention of Bodden. These inventions are

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analogous with each other and the present invention; therefore, a combination is proper.

Additionally, longitudinal cuts/grooves in catheter shafts are well known in the art to facilitate over the wire catheter procedures which enhance the ability of guidewire exchange during a procedure if another guidewire (e.g. longer guidewire) is needed. It is commonly known that this type of over the wire exchange is easier for the technician to perform and safer to the patient.

The motivation for the incorporation of the cut and guide member as taught by McDonnell would have been to utilize common knowledge in the art to enhance the ability of the technician to perform the procedure if a guidewire exchange was needed and to increase the safety to the patient during that type of procedure.

At the time of the invention, it would have been obvious to one skilled in the art to incorporate the cut into the wall of the catheter at the location of the apex since the wall thickness of the catheter is less thick in that region of the wall. It is known in the art that opening a longitudinal cut in a thick walled tube requires more force than opening the same longitudinal cut in a thin walled tube. Therefore, incorporating the cut as taught by McDonnell into the apex portion of the catheter shaft of Bodden would utilize common knowledge in the art to enhance the ability of the guide member to open the cut for the guidewire to enter or exit the lumen of the catheter.

Allowable Subject Matter

Claims 13-28 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

The prior art does not teach a catheter having a distal section including a catheter shaft with a

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guidewire shaft having a lumen disposed coaxially within the catheter shaft where an inflation lumen is formed between the interior surface of the shaft and the exterior surface of the guidewire shaft in combination with the a proximal end of the distal section being bonded to a distal end of a proximal section that has a interior surface having a plurality of arms and nodes defining a guidewire lumen and an inflation lumen being disposed within a node where the guidewire lumen of the proximal section is communication with the distal guidewire lumen and the two inflation lumens being in fluid communication.

The prior art most similar is McDonnell ('291, cited above) that teaches a catheter shaft having a biluminal proximal section that transitions to a co-axial distal section. However, there is no motivation in the art or commonly known to make a combination of the references to render the claims obvious.

Claim 2-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach the combination of a catheter shaft having a non-circular lumen with a plurality of alternating arms and nodes where the shaft comprises a first material and a crown portion of the node comprises a different material in combination with a cut extending between the interior surface and exterior surface of the shaft at an apex of one of the arms and a guide member that opens and closes the cut.

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Claim 6-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The prior art does not teach the combination of a catheter shaft having a non-circular lumen with a plurality of alternating arms and nodes where the exterior surface of the shaft includes a plurality of indentations each extending toward one of the arms in combination with a cut extending between the interior surface and exterior surface of the shaft at an apex of one of the arms and a guide member that opens and closes the cut.

Claim 10-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

See indication for allowability of claim 13 above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846.


The examiner can normally be reached on Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *CSW*.
September 18, 2004


NICHOLAS D. LUCCHESI
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